be disclosed except in five situations specified in section 14 (a) and (b). Standing alone section 14 would, accordingly, seem to require that EPA not disclose the fact that a particular chemical substance is manufactured or processed for commercial purposes if that fact would be exempt from disclosure under 5 U.S.C. 552(b)(4). However, section 14 is part of a larger statutory scheme in TSCA.

Section 8(b) requires EPA to publish a list of "each chemical substance which is manufactured or processed in the United States. Such list shall include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States" (emphasis added). The inventory is intended to inform the public which chemical substances are being manufactured or processed in the United States for commercial purposes. With this knowledge, the public would know the chemical substances to which they may be exposed and would be able to take an active participatory role in EPA actions under TSCA. This is clearly contemplated in sections 20 and 21 of TSCA that provide for citizens' civil actions and citizens' petitions. The inventory also has a regulatory purpose. It defines what is a "new chemical substance" for purposes of section 5(a) (1) (A). A "new chemical substance" is any substance that is not included in the inventory. If a chemical substance is a new chemical substance no person may manufacture it without first submitting to EPA a 90-day premanufacture notice, during which time the person may not manufacture the new chemical substance. If EPA has promulgated a testing rule under section 4 of TSCA, the delay period before manufacture might

be significantly extended.

Were there no section 14 requirement in TSCA, EPA would publish a list of all chemical substances manufactured or processed in the United States for commercial purposes without provision for claiming confidentiality. The public would know all chemical substances to which it may be exposed and would be able to participate fully under sections 20 and 21 of TSCA. Any person proposing to manufacture a chemical substance would be able to look at the inventory and determine whether the chemical substance was an existing chemical substance with a commercial purpose. If the substance appeared on the list, there would be no premanufacture notification requirements under section 5(a)(1)(A). If the substance did not appear on the list, the person would know it was a "new chemical substance." The Agency could conduct its investigation of all chemical substances in open public forums. However, were EPA to publish all chemical substances reported to EPA on the inventory, some persons submitting the information would suffer competitive harm when the fact that certain chemical substances have a commercial purpose was published.

Were EPA to give full effect to section 14 and publish a list of only those chemical substances for which the fact of manufacture or precessing for commercial purposes was not confidential, the public would have no information about those particular confidential chemical substances to which it may be exposed. The Agency would have to conduct its investigation of some chemical substances in camera. A manufacturer proposing to manufacture a chemical substance that did not appear on the list would not know whether the substance was a new chemical substance. Therefore, the manufacturer would be forced to give premanufacture notification under section 5(a)(1) (A). If, in fact, the chemical substance had been reported for the inventory fist, and, therefore, was not a new chemical substance, this new manufacturer would be placed at a competitive disadvantage by having to delay manufacture at least 90 days.

EPA has adopted the approach set out in § 710.7 of these regulations to balance the concerns of section 14 with those of sections 8(b) and 5(a). In choosing this approach, EPA looked to TSCA for guidance. It is clear that Congress intended section 5(a) (1)(A) premanufacture notification to apply only to chemical substances which are not currently manufactured for a commercial purpose. Congress created the section 8(b) inventory for the express purpose of determining this class of chemical substances. Congress did not seem to contemplate that the fact that certain chemical substances are manufactured or processed for commercial purposes would be claimed as confidential. Congress was clear in section 14 that confidentiality should be preserved to the maximum extent practicable without impairing the regulatory scheme of TSCA. The approach EPA has adopted preserves confidentiality to the maximum extent practicable while allowing the section 8(b) inventory to perform its regulatory function for purposes of section 5(a)(1)(A), premanufacture notification.

EPA will allow any manufacturer or processor submitting information to EPA under this rule to claim that a particular chemical substance should not be included on the inventory of chemical substances because the fact that the chemical substance is manufactured or processed for commercial purposes in the United States is a confidential trade secret. EPA will make a final confidentiality determination in accordance with the procedures in 40 CFR Part 2, Subpart B. If the fact that a particular chemical substance is manufactured or processed for a commercial purpose in the United States is confidential, a generic chemical name will be included in an appendix to the inventory; if it is not confidential, after 30 days notice to the submitter, the chemical identity will be included on the inventory. If any person reports a particular identity and does not claim it as confidential EPA will place the identity on the inventory.

Section 710.7(e) provides that a person claiming confidentiality for the specific chemical identity must provide a proposed generic chemical name to EPA. The proposed generic name must be only as generic as necessary to protect the identity of the particular chemical substance. Pursuant to § 710.7(f), EPA will review the proposed generic name. If the proposed generic name is not acceptable to EPA. EPA will consult with the submitter concerning alternative names. EPA may choose a name proposed by the submitter or a name proposed by EPA. In the latter case, EPA will notify the submitter 30 days in advance of publishing the final choice, during which time the submitter may seek a judicial remedy.

Placement of the generic name in the appendix to the inventory will serve two purposes. First, the public will know the generic types of confidential chemical substances to which it may be exposed. The public will be able to use this knowledge to participate in accordance with sections 20 and 21. Second, a manufacturer who is proposing to manufacture a substance not included on the inventory by name will be able to see whether the substance is described by one of the generic names. If it is not, it is a "new chemical substance," and the manufacturer must submit notices under section 5(a)(1) (A) at least 90 days prior to manufacture. If the substance does fall within one of the generic names, the manufacturer could come to EPA, show a bona fide intent to manufacture the substance, and be informed whether the specific proposed substance was included on the inventory. If it was, the manufacturer would be able to begin manufacture without delay. If it was not, it would be a "new chemical substance," and the manufacturer would have to submit notice under section 5 at least 90 days prior to manufacture. No person may manufacture a substance within a generic name unless EPA has notified the person that the particular substance is included in the inventory.

To determine whether or not such a manufacturer has a bona fide intent to manufacture the proposed chemical substance, EPA will require the manufacturer to submit a statement of present intent to manufacture the particular chemical substance, including a description of the research and development activities to date and the purpose of manufacture. In addition, EPA will require an elemental analysis, either an X-ray diffraction pattern of the substance (for inorganic substances) or a mass or alternative spectrum of the substance (for other substances), any additional spectra or data, including a sample of the substance in its purest form, that may be required to resolve uncertainties with respect to the identity of the substance. At the time such an inquiry is received, EPA will contact the original submitter and ask for an elemental analysis and either a mass or alternative spectrum or an X-ray diffraction pattern of the substance. Further, additional spectra or data may be required to resolve uncertainties with respect to the identity of the substance. EPA may require a sample of the substance in its purest form for comparison with that submitted by the inquiring manufacturer. Section 710.7(e) provides that any person asserting a claim of confidentiality must agree to make such information available to EPA upon request and must agree that EPA may disclose the fact that the specific chemical substance is included on the inventory to a manufacturer with a bona fide intent to manufacture the substance. (Failure to so agree or to furnish requested data results in waiver of the claim of confidentiality.)

If EPA determines that the manufacturer has a bona fide intent to manufacture the substance, EPA will disclose whether the substance in question is on the inventory. EPA scientists will compare the technical data submitted by the inquirer with that prepared by the manufacturer of the confidential chemical substance to determine whether the data from both sources are sufficiently similar to be consistent with a presumption that the chemical substances are the same. If EPA determines that the manufacturer has not shown a bona fide intent to manufacture the substance, EPA will not disclose whether the substance is on the inventory. The manufacturer will then have the choice of supplying further information to EPA to show bona fide intent to manufacturer the substance or of submitting premanufacture notification under section 5(a)(1)(A).

This approach will place some burden on manufacturers to come to EPA to show a bona fide intent to manufacture. However, this burden is less than the burden of section 5(a) (1) (A) premanufacture notification. Any manufacturer who does have a bona fide intent to manufacture a particular substance should know the information required to show that intent to EPA. This approach will discourage fishing expeditions by persons without a bona fide intent to manufacture and thereby protect trade secrets from disclosure to competitors. EPA does not view disclosure to a bona fide manufacturer to be a disclosure in violation of section 14. The trade secret that is being kept confidential is that the particular chemical substance is manufactured or processed for commercial purposes in the United States by anyone. If the inquiring manufacturer shows a bona fide intent to manufacture the particular substance, the manufacturer already knows that it can be manufactured for a commercial purpose. Telling the manufacturer that the substance is on the inventory does not reveal anything except that someone else already found a commercial purpose for the substance.

Maintaining specific chemical identities as confidential for purposes of the inventory has impacts beyond those on sections 8(b) and 5(a). It is conceivable that the Agency will decide to direct a section 4 testing rule to a confidential chemical, that the Agency will decide to promulgate a section 5(a) (2) significant new use rule on a confidential chemical, that the Agency will decide to promulgate a section 8 reporting rule on a confidential chemical, and that proceedings under section 20 and 21 of the Act may pertain to confidential chemicals. The Agency intends to honor the confidentiality of specific chemical identities to the extent practicable without impairing the Agency's ability to perform its duties under TSCA. This means that EPA may have to balance confidentiality with other TSCA needs at future times under other rules. TSCA section 14 (a) and (b) directs the Administrator to disclose information otherwise entitled to confidential treatment in certain circumstances. The Agency intends to rely on these authorities to the fullest extent provided by law.

A determination that an identity is confidential for purposes of the inventory may be reviewed if new facts suggest that confidential treatment is no longer appropriate.

Comment 94: Requiring substantiation at the time of submission of a claim that the identity of a chemical substance should not be placed on the inventory is overly burdensome. Such substantiation should only be required when necessary to respond to a Freedom of Information Act request.

Response: The Administrator disagrees with this comment. The requirement in TSCA section 8(b) that the Agency publish an inventory of chemical substances requires the Agency to make individual final determinations on the entitlement of the identity of a particular chemical substance to confidential treatment under the test of 5 U.S.C. 552(b) (4) before publication of the initial inventory. Under the procedures of 40 CFR Part 2, Subpart B, this determination is made on the basis of the substantiation of that claim provided by the person asserting the claim. In order for EPA to review, prior to publication of the initial inventory, all claims that the identity of a chemical substance is entitled to trade secret protection, substantiation of the claim must be submitted when the claim is asserted. Failure to submit substantiation of such a claim will be a waiver of the claim.

Comment 95: The statements for substantiating a claim for confidentiality on proposed Form C are too restrictive. A company must be allowed to state for itself the basis of its claim of confidentiality.

Response: The Administrator agrees with this comment. Any submitter claiming that the identity of a particular chemical sub-stance should not be included on the inventory must substantiate that claim. The substantiation must be in the form of a letter attached to Form C stating the submitter's basis for its claim of confidentiality and addressing a list of questions specified in the Form C instructions. The burden for substantiating a claim that the particular chemical identity should not appear in the inventory is greater than that for substantiating other confidentiality claims under the inventory because of the increased burden that will be placed on the public and future manufacturers under section 5(a) in not knowing all of the specific chemical identities reported for the inventory. Accordingly, companies should be very careful in claiming that specific identities are entitled to confidential treatment.

Comment 96: EPA should accept the gethe generic chemical name is too broad or misleading, request the submitter to modify the generic name. EPA should not substitute its judgment. EPA should not substitute its judgment for that of the submitter.

Response: The Administrator disagrees with this comment. Submitters will have an interest in submitting the broadest generic names possible. Since EPA is balancing competing considerations of confidentiality, the public's right to know, and the interests of manufacturers under section 5(a), EPA must take an active role in choosing a generic name that is only generic enough to protect the trade secret identity.

If EPA agrees with the generic chemical name proposed by the submitter and the chemical identity has been found to be confidential for purposes of the inventory, EPA will place the proposed generic name in an appendix to the inventory. If EPA believes that the generic name is too general so that it will not serve the purpose of informing the public and future manufacturers under section 5(a), EPA will consult with the submitter concerning more restrictive names. If EPA and the submitter are unable to agree on the generic name, EPA will choose a generic name, notify the submitter of the choice at least 30 days before inclusion on the inventory. The submitter may seek a judicial remedy under section 14. Unless a court intervenes, after the end of the notice period. EPA will place the generic name on the list.

Link of Company Name to Chemical Identity

Comment 97: The fact that a certain company manufactures a particular chemical substance may be a confidential trade secret. EPA should not publish company names on the inventory.

the inventory.

Response: The Administrator agrees with this comment. Section 710.7(a) permits a manufacturer, importer, or processor to claim that the link between the name of the manufacture, importer, or processor with a particular chemical substance is entitled to confidential treatment. The 8(b) inventory will consist only of a list of chemical substances reported to EPA. It will not include any information concerning which companies reported the chemical substances. A claim that particular chemical identity should not appear on the inventory (see comment 92) should not be made if the only confidential trade secret is the link between the company name and chemical identity.

If a claim of confidentiality is asserted regarding the link of company name with a particular chemical substance, it will be disclosed by EPA only to the extent permitted by, and by means of the procedures set forth in 49 CFR Part 2, Subpart B.

#### Production data

Comment 98: Site specific production data may be a confidential trade secret.

Response: Section 710.7(a) recognizes that production data may be entitled to confidential treatment and permits persons reporting production volumes to the Agency to assert a claim of confidentiality. Section 710.5(d) (4) of these final regulations requires companies to report broad production ranges, rather than the more specific production volumes which would have been required by the August 2, 1977 proposed rules. This should eliminate the need for many claims of confidentiality.

Comment 99: Does EPA plan to publish aggregates of data from the inventory, especially confidential data? If so, in what way will EPA protect the confidential data?

Response: EPA is considering alternative ways of publishing aggregates of production and other data submitted for chemical substances. However, before EPA publishes any aggregation that includes data that have been claimed as confidential, EPA will develop aggregation procedures designed to protect the confidentiality of the underlying data and will publish these procedures for public comment.

### National Security Information

Comment 100: Some information required by these regulations may be entitled to confidential treatment because of national security reasons. How will EPA handle assertions of confidentiality on these grounds?

Response: Section 22 of TSCA states that EPA "shall waive compliance with any provision of this Act upon a request and determination by the President that the requested waiver is necessary in the interest of national defense." The President has not requested that any waiver be granted with regard to the inventory regulations. Accordingly, any person subject to the reporting requirements of these regulations must report any substance subject to these regulations even if that substance is being made for national defense purposes. Production for national defense purposes is a commercial purpose as defined in these regulations. Any person reporting under these regulations must report all information required to be reported concerning sites, production, etc., regardless of whether that information relates to national defense.

If a person required to report under these regulations would be reporting information that is or may be classified as national defense information under Executive Order 11652, that person should not report to CAS. Instead, the person must contact Kenneth Olsen, Office of Toxic Substances, EPA, 401 M Street, SW., Washington, D.C. 20460, by letter stating that the person may be required to report classified information to EPA under these regulations. Do not report the classified information to EPA that time. EPA will send the person a letter with specific instructions how to proceed. This will include forwarding the information to the particular systems program office that is managing the particular work involved. The systems program office will examine the specific information and mark it with the appropriate classification. The information will then be sent to EPA where it will be kept in a special system separate from the remainder of the inventory information. EPA will have an office with personnel authorized to receive and use classified information.

Please note, if the information in question is also considered to be confidential business information by the person submitting it, that person must assert all claims of business confidentiality at the time, the information is submitted to EPA in accordance with these regulations and the instructions on the forms.

#### Freedom of Information Requests

Comment 101: How will EPA handle Freedom of Information Act requests for the confidential information submitted under these regulations?

Response: EPA will allow submitters to claim any item of information submitted to EPA under this rule as confidential. The reporting forms are designed to allow all confidentiality claims to be made by checking boxes on the forms. In addition, the certication statement has been written to allow a submitter to substantiate all claims of confidentiality, except chemical identity, on the reporting form. By using this approach, EPA intends to minimize the need to go back

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confidentiality will not change. EPA has established a Task Force to recommend procedures to the Administrator to provide for the security of confidential information submitted to EPA under TSCA.

The Task Force will work quickly so that EPA

pending this review.

not disclosed?

of the work of the Task Force appeared in

will have procedures adopted by April 30, 1978, the end of the inventory reporting period. The Task Force will hold several public meetings and will publish proposals for publice comment. The final security procedures will be published. A more detailed discussion

to specific submitters to require them to sub-

stantiate confidentiality claims. This will en-

able EPA to deal more effectively with the

anticipated large volume of Freedom of In-

formation Act requests that will be received

under TSCA.
All information submitted under these

rules will be computerized. All confidential information (except confidential identities)

will be specially coded if a claim of confidentiality was made and substantiated at the time of submission.

confidential information requested; that information will be disclosed to the requester.
The computer will then print out the re-

quested confidential information. The requester will receive an initial denial of the request for any confidential information in request for any confidential information in accordance with the procedures in 40 CFR Part 2, Subpart B. EPA will then make a final confidentiality determination, inform the requester of the decision, give 30 days notice to the submitter if the determination.

notice to the submitter if the determination is that the information is not entitled to confidential treatment, and then disclose any

EPA will not have computer access capability until at least 6 to 8 months after the

end of the initial reporting period. During that period the Agency will be processing submitted information. The actual forms submitted to EPA will not be filed in a retrievable form. If EPA receives FOIA requests orior to the end of the processing period it.

prior to the end of the processing period it will be virtually impossible to search for the requested information. Consequently, EPA requests that FOIA requesters refrain from making FOIA requests for inventory informa-tion until the end of the processing period. In some cases, when responding to FOIA requests, EPA will be forced to give uninformative denials. If a requester asks a question in such a way that to answer the request would reveal confidential information, EPA will answer the request in the following fashion: "Your request is denied either because the records you request are entitled to confidential treatment under 5 U.S.C. 552(b) (4) and EPA may not disclose them under section 14 of TSCA, or because no such records exist." The requester will have a final EPA denial and will be able to go to a Federal district court to seek further review. The confidential information will be protected,

Confidentiality Procedures and Security Comment 102: How will EPA determine the entitlement of information to confidential treatment; what procedures will it follow to ensure that confidential information is

Response: The Agency's business confidentiality regulations are contained at 40 CFR Part 2. Subpart B. These regulations will be amended to take into account specific modifications required by TSCA section 14, such as the extension of the notice period to 30 days. The basic approach for determining

non-confidential information.

When EPA receives FOIA requests, EPA will prepare a computer print out of the nonthe Federal Register, 42 FR 57984, November 7, 1977

Access to Confidential Information by States Comment 103: EPA should allow access to confidential information by the states.

Response: EPA does not have general authority to disclose confidential TSCA information to the States. Section 14(a) lists the parties to whom confidential informa-tion may be disclosed. In certain circumstances, EPA may disclose confidential in-

IMPORTANT: Sofore completing this form, enoughly read the EPA public Substance inventory". That booklet contains instructions (

formation to other Federal agencies, to TSCA contractors, when relevant to a proceeding under TSCA, or when necessary to protect health or the environment against an unreasonable risk of injury. Accordingly, confidential information may only be disclosed to a State if the State is an EPA contractor, if the State is a party to a TSCA proceeding, of when necessary to protect health or the environment from an unreasonable risk of injury.

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IMPORTANT: Substance Inventory". That be U. S. ENVIRONMENTAL PROTECTION AGENCY CHEMICAL SUBSTANCE INVENTORY REPORT 4FA USE ONLY H. CORPORATION MID

II. PLANT SITE NAME/ADDRESS PORM DUN & BRADSTREET NO. (e) CORPORATION (d) PRODUCTION (c) SITE LIMITED (b) MPORT MANUFACTURE SITE LIMITED MANUFACTURE CIASS 1 SPECIFIC CHEMICAL NAME CAS REGISTRY NUMBER (IF KHOWN)

EPA FILE COPY

NUMBER

# **RULES AND REGULATIONS**

& U. S. DOVERHARM PERMITS CATACE - 1077-141-279 a.s.

	U. S. ENVIRONMENTAL PRO VOLUNTARY PRODUCT TR	OTEC	TK	ON AGENCY	FORM
	[IM CONJUNCTION WITN THE TOXIC SUBSTANCES ( L CETFFCATION STATEMENT, I hereby carrify that, to the best et im  import and that of consponent chemical substances that are permit  agree to permit access to, and the copying of records, by a duty our  Act, to document any information reported here.				ies a product which I manufacture a reported either by me or by others, soe with the Toicic Substances Control
	MID BY A USE ONLY SOMEWARD IN CORPORATE NAME/ADDRESS			DATE HAMESTEE HAMESTEEL PRINCIPAL TECHNICAL CON	I (TYTE OR POSHT)
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